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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,603	02/04/2005	Hiroshi Kase	00005.001205.1	4143

5514 7590 11/23/2009

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EXAMINER	
JAVANMARD, SAHAR	

ART UNIT	PAPER NUMBER
1627	

MAIL DATE	DELIVERY MODE
11/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,603	KASE ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 8-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 8-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/22/09; 7/29/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to Applicant's arguments filed on July 29, 2009. Claim(s) 1-5 and 8-12 and are examined herein.

Response to Arguments

Applicant's arguments with respect to the 103(a) rejection of claims 1-5 and 8-12 as being unpatentable over Suzuki et al. (U.S. Patent No. 5,587,378; 1996) of record in view of Trenkwalder (Clinical Neuroscience, 1998) of record in further view of Evidente (*Movement Disorders*, 2000) has been fully considered but is not persuasive.

Examiner is maintaining the argument that Applicant's compounds which are taught by Suzuki as being administered for the treatment of Parkinson's would necessarily be useful in the treatment of RLS. As previously set forth on record, because Trenkwalder teaches that 60-90% of PD patients complain about a variety of disease-related or secondary mechansims of which include restless leg syndrome and/or nocturnal myoclonus it would be obvious to administer said compounds to also treat indivuals with restless syndrome or nocturnal myoclonus because there is an overlapping population of patients that have both PD and restless leg syndrome and/or nocturnal myoclonus. As is well known in the art, there is no cure for Parkinson's disease and the treatments that are available today are just that, treatment for the syptoms thereof. Therefore, based on the teachings of Trenkwalder, RLS and nocturnal myoclonus are symptoms of Parkinson's disease and if Suzuki teaches that xanthine

derivatives has the potential of treating Parkinson's diease, that is the symptoms therof, then one of ordinary skill in the art would consider RLS and nocturnal myoclonus to be included in the symptoms to be treated.

Examiner has considered Dr. Kanda's affidavit but is not persuasive. It is not Examiner's contention that Parkinson's disease increases the risk of RLS or nocturnal myoclonus or vice versa. As discussed abovem, the Examiner considers RLS and nocturnal myoclonus to be symptoms in Parkinson's disease patients. As taught by Trenkwalder, it would seem that the 60-90% of patients that complain about said secondary mechanisms would benefit from a treatment agent that useful in treating such a disease. Thus, it would be obvious that by administering PD with Applicant's compound, that one would also be able to treat the symptoms thereof including restless leg syndrome and/or nocturnal myoclonus in said overlapping population of patients.

Furthermore, Applicant argues that compounds effective in treating RLS are effective because they have dopaminergic action in the central nervous system not necessariy because they arbitrarily treat Parkinson's disease. In response to this Examiner respectfully points out that Suzuki teaches the effect of said xanthine derivatives on the locomotor activity in the Parkinson's disease model (see column 44, example 3). As taught by Suzuki it is known that in the strain of mouse employed in this particular experiment, the striatal dopamine is remarkably decreased and locomotor activity is depressed. In table 5, it is further taught that selected xanthine derivatives taught by Suzuki are successful in regaining locomotor activity. Thus it is evident that these compounds indeed play a role in the dopaminergic system.

The 103(a) rejection is hereby maintained and is modified in view of Applicant's amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (U.S. Patent No. 5,587,378; 1996) of record in view of Trenkwalder (Clinical Neuroscience, 1998) of record in further view of Evidente (*Movement Disorders*, 2000).

Suzuki teaches a method for administering xanthine derivative compounds, in particular, (E)- 8-(3,4-dimethoxystyryl)-1,3-diethyl-7-methylxanthine (Example 8, column 55, lines 27-57), in an effective amount to patients suffering from Parkinson's disease (PD) (column 3, lines 34-36; claim 1). In particular, Suzuki teaches the adenosine A2 receptor antagonistic activity of the disclosed xanthine compounds (column 1, lines 64-67).

Suzuki does not explicitly teach restless legs syndrome and nocturnal myoclonus.

Trenkwalder teaches the frequency of sleep complaints in patients with PD is estimated between 60-90% and a variety of either disease-related or secondary mechanisms and the various treatments contribute to the development of different sleep disturbances. Trenkwalder further teaches these comprise slight, fragmented sleep with increased number of arousals and awakenings, and PD-specific motor phenomena such as nocturnal immobility, rest tremor, eye-blinking, dyskinesias, and other phenomena such as periodic and nonperiodic limb movements in sleep, restless legs syndrome, fragmentary myoclonus, and respiratory dysfunction in sleep (abstract). Trenkwalder teaches that restless legs syndrome frequently occurs in patients with Parkinson's disease at an advanced stage (page 108 column 3). Further, Trenkwalder teaches that another motor phenomenon that occurs in Parkinson's disease is nocturnal myoclonus (page 108, column 3).

Evidente teaches that RLS demonstrates favorable response to antiparkinsonian medications like levodopa and dopamine agonists.

It would have been obvious to one of ordinary skill in that art at the time of the invention to have administered the compound(s) of formula I to PD patients as taught by Suzuki and used them to also treat patients with restless legs syndrome and nocturnal myoclonus. The motivation, provided by Trenkwalder, teaches that these motor disturbances are commonly observed in individuals with Parkinson's disease. Thus if a patient with PD is administered the compound of formula I, it would be obvious that the

restless legs syndrome and nocturnal myoclonus symptoms would also necessarily be treated. Additionally, in further view of Evidente, it is taught that RLS responds well to antiparkinsonian drugs such as levodopa and dopamine agonists. Thus one would be further motivated to treat RLS with Applicant's compounds because one would expect with a reasonable degree of success that because RLS responds to antiparkinsonian treatment agents such as levodopa and dopamine agonists that it would also respond to Applicant's compounds taught by Suzuki which are also antiparkinsonian agents and play a role in the dopaminergic nervous system.

Conclusion

Claims 1-5 and 8-12 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627